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| 10/713,772 | 11/14/2003 | Yoshihiro Mori | 09496/0200199-US0 | 8762 |

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DARBY & DARBY P.C.
P.O. BOX 770
Church Street Station
New York, NY 10008-0770

| EXAMINER | |
|---|---|
| CRAIG, PAULA L | |
| **ART UNIT** | **PAPER NUMBER** |
| 3761 | |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/713,772 | MORI ET AL. | |
| | Examiner | Art Unit | |
| | PAULA L. CRAIG | 3761 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *06 March 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-3,8 and 9* is/are pending in the application.

4a) Of the above claim(s) *9* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3 and 8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Continued Examination Under 37 CFR 1.114*

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 4, 2008 has been entered.

### *Response to Arguments*

2. The objections to Claims 1 and 8 are withdrawn in light of the amendment filed February 4, 2008. The rejection of Claim 8 under 35 USC 112, first paragraph, is withdrawn in light of the amendment filed February 4, 2008; however, a new rejection under 35 USC 112 is made, as indicated below. As to the rejections under 35 USC 103, Applicant's arguments filed February 4, 2008 have been fully considered but they are not persuasive. Applicant argues that Brugger does not disclose or suggest obtaining two separate ratios and then comparing the two separate ratios to obtain an evaluation value. However, the requirement for the use of two separate ratios is essentially a requirement that the evaluation of the measurements obtained by the hematocrit sensors be done indirectly through ratios, rather than directly through evaluation of the hematocrit data itself or indirectly through the use of some other

suitable mathematical formula. Applicant has provided no evidence, such as laboratory results, that show that obtaining two separate ratios and comparing the two ratios to obtain an evaluation value has any effect on the output of the blood purification device as compared to the prior art. No particular relationship between the ratios is claimed; for example, a relationship between the ratios of Hta/Htv=Qb/Quf, Hta/Htv =900Qb/Quf, or Hta/Htv=1-Qb/Quf is consistent with the claims. Each of these equations can also be expressed in a form which is exactly equivalent but does not involve a ratio. Brugger teaches making appropriate calculations in relation to the blood pump, the blood purifier, the first and second hematocrit values, and the blood flow rate (col. 6, lines 43-63, col. 21, line 24 to col. 24, line 56). The selection of a suitable mathematical formula for making such calculations for a particular system of sensors, pumps, and instrumentation is within the ability of a person of ordinary skill in the art.

3. Though not necessary to the above analysis, the claims are directed to a blood purification device, which is an apparatus. All of the claimed structural elements are shown in the prior art. Applicant's claim limitations drawn to the operation of the calculating unit are considered by the Examiner to be statements of the intended use of the device. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987), and *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967). In addition, the phrase "can be" in Claim 1, line 13 suggests that at least part of the operation of the calculating unit is optional.

### *Specification*

4. The objection to the specification as failing to provide proper antecedent basis for the claimed subject matter is maintained for the reasons of record. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: The specification does not teach which of the variables and equations disclosed in pages 12-30 of the specification corresponds in Claim 8 to the claimed second measurement value, the second theoretical value, the difference between the second measurement value and the second theoretical value, the adjusted blood flow rate, and the second predetermined acceptable ratio difference.

### *Claim Objections*

5. Claims 1-3 and 8 are objected to because of the following informalities: In Claim 1, line 12, "theoretic" should be "theoretical" due to lack of antecedent basis. In Claim 8, line 12, "said difference" lacks antecedent basis. In Claim 8, lines 17-18, "the second predetermined acceptable ratio difference" lacks antecedent basis. Appropriate correction is required.

### *Claim Rejections - 35 USC § 112*

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-3 and 8 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. For Claim 1, lines 14-17, the ratio Hta/Htv is taught in the specification as relating to the ratio Quf/Qb, rather than Qb/Quf as claimed (see specification, page 12, line 19, page 13, lines 6-11; note that Qb/Quf is described on page 37 of the specification as relating to a hemoglobin concentration ratio Hba/Hbv, rather than to the hematocrit ratio Hta/Htv).

### *Claim Rejections - 35 USC § 103*

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. Claims 1-3 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brugger (US 6,554,789).

10. For Claim 1, Brugger teaches a blood purification device having a blood circuit with an arterial blood circuit and a venous blood circuit (Fig. 11, col. 1, lines 15-17, and col. 9, line 24 to col. 10, line 24). A blood pump is disposed in the arterial blood circuit (blood pump 92, Fig. 11, col. 10, lines 1-17). A blood purifier is connected between the arterial blood circuit and the venous blood circuit, and configured to purify blood flowing in the blood circuit (hemofilter 34, Fig. 11 and col. 5, lines 58-64). A first measuring unit is disposed in the arterial blood circuit configured to measure a first hematocrit value Hta of the arterial blood circuit (upstream sensor measuring pre-treatment hematocrit, col. 24, lines 8-14). A second measuring unit is disposed in the venous blood circuit and configured to measure a second hematocrit value Htv of the venous blood circuit (downstream sensor for post-treatment hematocrit, col. 24, lines 14-43). Brugger teaches a calculating unit which obtains an evaluation value which can be used to evaluate operation of the blood purification device by comparing the first measured hematocrit value Hta and the second hematocrit value Htv (col. 21, lines 24-53, col. 22, lines 52-59, col. 24, lines 21-43). Brugger teaches a theoretical ratio value obtained by a formula using a preset blood flow rate Qb, and a preset water removal rate Quf (preset blood flow rate Qb corresponds generally to blood flow rate BFR; preset water removal rate Quf corresponds generally to filtration fraction value FF; the equation [RFR +UFR]/FF includes a ratio; col. 6, lines 43-52, col. 20, lines 41-67, col. 21, lines 34-42, col. 22, lines 56-59, col. 24, lines 21-26, col. 31, line 36 to col. 32, line 14). Brugger

teaches an evaluation unit (col. 21, line 1 to col. 22, line 59, col. 24, lines 21-46, col. 31, lines 9-18). Brugger teaches a reporting unit configured to report a trouble condition for at least one of the blood pump and the blood purifier when appropriate (col. 6, lines 53-63, col. 7, lines 39-58, col. 22, lines 47-51, col. 24, lines 35-45, col. 26, lines 7-11 and 30-52, col. 31, lines 9-18). Brugger teaches that the device is capable of detecting leaks (col. 6, lines 53-59, col. 7, lines 39-43; note that Applicant's specification teaches that leaks are one of the trouble conditions to be detected by the sensors, see specification, pages 13 and 31). Brugger does not expressly teach a measured ratio value Hta/Htv; the theoretical ratio value being Qb/Quf; comparing the measured and theoretical ratio values to obtain an evaluation value; the evaluation unit evaluating whether the evaluation value is larger than a first predetermined acceptable ratio difference; or the reporting unit reporting a trouble condition when the evaluation value is larger than a predetermined value. Applicant's specification does not disclose that the evaluation unit evaluating whether the evaluation value is larger than a first predetermined acceptable ratio difference serves any stated purpose or solves any particular problem as compared to the prior art. Various mathematical approaches exist for calculating whether a pair of hematocrit sensors measuring a blood concentration are producing the expected results; the effectiveness of each approach from the patient or clinician's point of view depends not only on the precise mathematical formula used, but also on the configuration of the system and on the limits considered tolerable. Applicant has not disclosed that the process of comparing ratios produces any differences from the prior art in the device's output to the patient. It is well known in the

art of feedback sensors to report a trouble condition when the theoretical values produced by a sensor do not match the expected results within certain limits. Given that Brugger teaches all the structural limitations of the claims, including a pair of measuring units measuring pre- treatment hematocrit and post-treatment hematocrit in the arterial and venous blood circuits, as well as detecting leaks and other trouble conditions, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Brugger to use a suitable mathematical formula to calculate when the theoretical values differ enough from the measured values to determine that a trouble condition exists.

11. For Claim 2, Brugger teaches a blood purifier (hemofilter 34, Fig. 11 and col. 5, lines 58-64). A water removing unit is connected to the blood purifier and configured to remove water from the blood flowing in the blood purifier (ultrafiltration and removal of waste fluid, col. 6, lines 34-60, col. 7, lines 26-30, col. 20, lines 41-67, col. 21, line 24 to col. 22, line 3, and col. 23, line 43 to col. 24, line 34). The preset purifying rate is the same as the preset water removal rate of the water removing unit (col. 21, line 24 to col. 24, line 34).

12. For Claim 3, Brugger teaches a substitution fluid supplying unit configured to supply a substitution fluid into the blood circuit (replacement fluid, col. 1, lines 37-42, col. 6, lines 1-7, and col. 20, lines 47-54). Brugger teaches the calculating unit being configured to calculate a theoretical ratio value based on parameters using a preset substitution fluid supplying rate of the substitution fluid supplying unit and a filtration rate of the blood purifier in addition to the preset blood flow rate and the preset water

removal rate (col. 6, lines 43-63, col. 20, line 41 to col. 22, line 59, and col. 23, line 43 to col. 24, line 34). Brugger teaches the reporting unit being configured to report a trouble condition for at least one of the blood pump, the blood purifier and the substitution fluid supplying unit (col. 24, lines 35-45, col. 26, lines 7-11 and 30-52, col. 31, lines 9-18).

13. For Claim 8, Brugger teaches the blood pump being configured to adjust the preset blood flow rate to an adjusted blood flow rate (col. 21, lines 24-64). Brugger teaches the calculating unit being further configured to calculate a second measurement value and a second theoretical value, the second measurement value referring to blood concentrations measured by the first measuring unit and the second measuring unit while the blood pump is operated at the adjusted blood flow rate and the blood purifier is operated at the preset blood purifying rate, and a second theoretical value referring to a blood concentration ratio obtained by at least one formula based on parameters including the adjusted blood flow rate of the blood pump and the preset blood purifying rate of the blood purifier (col. 24, lines 21-45, col. 30, lines 30-49, col. 31, lines 42-67; note that measurement is continuous, rather than a one-time-only measurement, and that the values of all the variables can be changed depending on which variable the user desires to hold constant; note also that the second theoretical value is not required by the claims to be different from the first theoretical value). Brugger teaches monitoring the performance of the device over time to verify the function and integrity of the pumps and the flow paths, including trouble conditions (col. 24, lines 38-43). Brugger does not expressly teach the second measurement value being a ratio. Brugger does not expressly teach the evaluation unit being further configured to

evaluate whether the difference between the second measurement value and the second theoretical value indicates a trouble condition, or the reporting unit reporting a trouble condition for the blood purifier when the difference between the second measurement value and the second theoretical value is at a first value which is different than the second predetermined acceptable ratio difference, or reporting the trouble condition for the blood pump when the difference between the second measurement value and the second theoretical value is at a second value which is different than the second predetermined acceptable ratio difference. In light of Brugger's teaching of continuous monitoring and dynamic adjustment of the system, it would have been obvious to one of ordinary skill in the art to modify Brugger to include the evaluation unit being further configured to evaluate whether the difference between the second measurement value and the second theoretical value indicates a trouble condition, to determine whether conditions have deteriorated or a leak has started. Given that Brugger teaches all the structural limitations of the claims, including a pair of measuring units measuring hematocrit in the arterial and venous blood circuits to detect leaks and other trouble conditions, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Brugger to use an appropriate method to calculate when the theoretical values differ enough from the measured values to determine that a trouble condition exists in the blood purifier or the blood pump respectively and report the trouble condition for each component, for the same reasons as described above for Claim 1 in paragraph 10.

## *Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PAULA L. CRAIG whose telephone number is (571)272-5964. The examiner can normally be reached on M-F 8:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Paula L Craig
Examiner
Art Unit 3761

/P. L. C./

/Tatyana Zalukaeva/
Supervisory Patent Examiner, Art Unit 3761